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September 7, 2000

VIA FEDEX

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket No. 78N-0038
Sunscreen Drug Products For Over-The-Counter Human Use

Dear Madam/Sir:

On behalf of The Estēe Lauder Companies Inc. (Estee Lauder), on September 6, 2000, we submitted comments in response to the Food and Drug Administration's (FDA's) reopening of the administrative record on Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph; Extension of Effective Date, Reopening of Administrative Record. 65 Fed. Reg. 36319 (June 8, 2000).

On further review of those comments, we noticed several grammatical errors. We have corrected those errors and we are enclosing four copies of the corrected version of the comments. This version contains no substantive changes, only the minor corrections mentioned. Please substitute the enclosed comments for those that were previously submitted.

If you have any questions, please do not hesitate to contact the undersigned.

Sincerely,

Marsha C. Wertzberger
Counsel to The Estēe Lauder
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Ivan J. Wasserman
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78N-0038

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September 6, 2000

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Food and Drug Administration
5630 Fishers Lane
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Re: Docket No. 78N-0038
Sunscreen Drug Products For Over-The-Counter Human Use

Dear Madam/Sir:

On behalf of The Estēe Lauder Companies Inc. (Estee Lauder), we are submitting these comments in response to the Food and Drug Administration's (FDA's) reopening of the administrative record on Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph; Extension of Effective Date, Reopening of Administrative Record. 65 Fed. Reg. 36319 (June 8, 2000).

Estee Lauder is one of the world's leading manufacturers of cosmetic products. As both a member of the Cosmetic, Toiletry, and Fragrance Association (CTFA) and on its own, Estee Lauder has a long history of participating in FDA rulemaking proceedings. Estee Lauder appreciates the agency's thoughtful consideration of these and all the previous comments that it has submitted.

On August 4, 2000, and September 6, 2000, CTFA submitted comments to the agency requesting that FDA revise the final sunscreen monograph to permit certain labeling modifications for all sunscreen products ("CTFA's Comments"). Those labeling modifications relate to the format requirements mandated by the OTC labeling content and format rule, 21 C.F.R. § 201.66 (the "OTC Label Rule"), as well as label information such as the indications and directions for sunscreen products. Estee Lauder agrees with and supports CTFA's comments. However, as discussed below, we believe that the case for modified labeling is particularly compelling for color cosmetic products for the face that contain sunscreens ("Facial Make-Up With Sunscreens"). Facial Make-Up With Sunscreens include all color cosmetics applied to the face that contain sunscreens.

ACTION REQUESTED

Estee Lauder requests that the agency revise the Sunscreen Monograph to: (1) permit all Facial Make-Up With Sunscreens to use the OTC labeling format for Sunscreen Small Parts of the Face Products regardless of whether such products meet the requirements of 21 C.F.R. § 201.66(d)(10) (the 60% rule); (2) permit the use of truthful and nonmisleading indications for Facial Make-Up With Sunscreens such as "protects against the harmful rays of the sun"; (3) permit flexibility to use appropriate directions and provide other useful information for Facial Make-Up With Sunscreens; and (4) not require the direction to consult a doctor for children under 6 months of age for Facial Make-Up With Sunscreens. Estee Lauder is aware that Australia and Canada provide similar labeling exemptions for Facial Make-Up With Sunscreens.

As discussed below, there is no rational basis for treating all Facial Make-Up With Sunscreens differently than sunscreen products intended for use on specific, small parts of the face. Further, Facial Make-Up With Sunscreens constitute a unique class of sunscreen products because of (1) the nature of the packaging of such products; (2) the special role the products play in the protection of public health; and (3) the likelihood that the use and availability of the products will decrease as a result of unnecessary or inappropriate labeling requirements.

RATIONALE FOR REQUESTED ACTION

Small Parts of the Face Exemption

Like all sunscreen products, Facial Make-Up With Sunscreens have a long history of safe use and do not present any of the safety concerns that triggered the OTC Label Rule as discussed in CTFA's Comments. In the Final Sunscreen Monograph, the agency provided modified labeling requirements for sunscreen "products labeled for use only on specific small areas of the face (e.g. lips, nose, ears, and/or around eyes)" that meet the criteria established in 21 C.F.R. § 201.66(d)(10)(modified OTC labeling requirements for small packages), and additional modifications for lipsticks. 21 C.F.R. § 352.52(f) (the "Small Parts of the Face Exemption"). Indeed, the agency has done away with many of the requirements of the OTC Label Rule, and even the need for directions, for lipsticks with sunscreens.

As discussed in the preamble to the Final Sunscreen Monograph, the agency allowed the Small Parts of the Face Exemption after considering the agency's six "Exemption Criteria,"[1/] as well as three additional factors: (1) "the intended uses of these products," (2) "the overall safety profile of these products," and (3) "the limited areas to which these products are applied." 64 Fed. Reg. 27666, 27682 (May 21, 1999).

As discussed in detail in CTFA's Comments, all sunscreen products meet five of the six Exemption Criteria, *i.e.,* they (1) have a high therapeutic index; (2) carry extremely low risk in actual consumer use situations; (3) provide a favorable public health benefit; (4) require no specified dosage limitation; and (5) require few specific warnings, and no general warnings. Facial Make-Up With Sunscreens also meet the sixth Exemption Criterion: such products are typically packaged in small amounts. Thus, Facial Make-Up With Sunscreens meet the six Exemption Criteria as certainly as do Small Parts of the Face products.

The three additional factors enumerated in the preamble to the Sunscreen Monograph also apply to all Facial Make-Up With Sunscreens as well as they do to Small Parts of the Face products.

First, the intended use of a Small Parts of the Face product is to protect the part of the face to which it is applied from the sun's harmful rays as well as to provide the intended cosmetic uses of the product (color, moisture). The intended use of Facial Make-Up With Sunscreens is identical.

1/ As discussed in CTFA's Comments, the six "Exemption Criteria" for sunscreen products that were identified by FDA in the preamble to the OTC Label Rule are:

1. Typically packaged in small amounts;
2. High therapeutic index;
3. Carry extremely low risk in actual consumer use situations;
4. Provide a favorable public health benefit;
5. Require no specified dosage limitation;
6. Require few specific warnings and no general warnings.

See 64 Fed. Reg. 13254, 13270 (Mar. 17, 1999).

Second, Facial Make-Up With Sunscreens and Small Parts of the Face products have identical "overall safety profiles." The active ingredients in both types of products are the same, and consumers are equally familiar with the proper use of both types of products. Simply put, the fact that a product may be applied to a slightly larger area of the face (such as the cheeks instead of the nose) does not suggest that it has a different safety profile.

The only possible way to differentiate these two classes of products is under the agency's third additional factor "the limited areas to which these products are applied." However, that distinction cannot serve as a rational basis for treating these products differently for labeling purposes. Facial Make-Up With Sunscreens are intended to be applied to a limited area of the body – the face. No product is intended to be used on the *entire* face (lip and eye products are typically special products). Therefore, all face products are intended to be used on a part or parts of the face. Are cheeks a "specific small part of the face?" Forehead? Chin? Jawline? These are all areas to which Facial Make-Up With Sunscreens are intended to be applied. There is no rational basis for requiring one set of labeling for a "foundation" product, and another set of labeling for "nose foundation," "cheek foundation" and "chin foundation" products. As discussed above, all of the Exemption Criteria apply equally to both types of products. The same minimal information is needed for the safe and effective use of the products. The fact of the matter is, if a consumer can use a lipstick product safely and effectively, she can use a rouge product safely and effectively with the same labeling information.

Regardless of the size of the container, Facial Make-Up With Sunscreens meet all of the Exemption Criteria and the three other factors considered by FDA for the Small Parts of the Face Exemption. While Facial Make-Up With Sunscreens are "typically packaged in small amounts," for the reasons discussed herein and in CTFA's Comments all Facial Make-Up With Sunscreens should be permitted to use this modified labeling, not just those that meet the specific size requirements of § 201.66(d)(10).

The agency has repeatedly expressed its concern that the OTC Label Rule may have the effect of causing manufacturers to stop marketing certain products and that, in such situations, appropriate modifications to the OTC Label Rule should be permitted. For example, in the preamble to the OTC Label Rule the agency stated:

> The agency agrees that there may be limited instances in which a labeling requirement may discourage manufacturers from marketing certain products for

> drug use (e.g. lipsticks containing sunscreen or lip balms containing skin protectant ingredients). These products, when they contain an ingredient intended to provide a therapeutic effect, do provide significant public health benefits to consumers.

64 Fed. Reg. at 13270.

Moreover, one of the reasons that FDA allowed modified labeling for Small Parts of the Face products was because "the agency agrees that excessive labeling requirements may discourage manufacturers from marketing" the products, " which provide significant public health benefit." 64 Fed. Reg. at 27681.

The agency could have had Facial Make-Up With Sunscreens specifically in mind when it expressed these concerns (of course one of the two examples - a lipstick containing sunscreen - is Facial Make-Up With Sunscreens). Unlike a product whose primary purpose is to provide sunscreen protection, Facial Make-Up With Sunscreens would retain their essential character as make-up even if the sunscreen were removed. Indeed, some consumers would probably not be aware that the product had changed. Thus, there is a very real possibility that manufacturers of Facial Make-Up With Sunscreens would simply remove the sunscreen ingredients from the products if flexible labeling options were not available. If that happens, consumers would be deprived of the significant health benefit provided by the sunscreens.

Uses

The sunscreen component of Facial Make-Up With Sunscreens does, of course, provide protection from sunburn. However, that is not the intended use of most Facial Make-Up With Sunscreens. The primary intended use is to provide color to parts of the face, and the secondary intended use is to protect the skin against damage caused by day-to-day exposure to the sun. Therefore, requiring the "sunburn" indications would require inappropriate and misleading labeling for most Facial Make-Up With Sunscreens. Accordingly, FDA should modify the final sunscreen monograph to permit truthful and nonmisleading indications for Facial Make-Up With Sunscreens, such as "protects against the harmful rays of the sun."

Directions

Directions are useful for Facial Make-Up With Sunscreens. However, in order to be useful, directions must be permitted to differ from those specified in the Monograph. There is a wide variety of Facial Make-Up with Sunscreens available, and, again, the primary use of the products is as make-up. Therefore, flexibility is necessary to craft appropriate directions and provide other useful information.

Moreover, the direction to consult a doctor for children under 6 months of age is clearly unnecessary for Facial Make-Up With Sunscreens. These products are color cosmetics intended primarily to impart color to the skin. Unlike traditional sunscreen products, they could not reasonably be expected to be used on children under six months old. Therefore, this direction is not needed for the safe and effective use of the products.

SUMMARY

Consumers understand that sunbathing and prolonged exposure to the ultraviolet rays of the sun can cause a variety of adverse health consequences, including, most significantly, skin cancer. There is less consumer understanding that daily, intermittent exposure to the sun can have the same deleterious consequences.

Consequently, the inclusion of sunscreens in daily use make-up products is very important to protect the public health. The public does not apply primary sunscreen products to wear in the office, even if they walk a mile to the office and eat their lunch outside in the park. However, consumers that use Facial Make-Up With Sunscreens will be protected from the damaging effects of the sun. Thus, as recognized by the agency, there is an important public health interest in encouraging the inclusion of sunscreens in daily use cosmetic products. However, unless the agency permits the modified labeling discussed herein, the inclusion of sunscreens in Facial Make-Up Products may decrease.

Facial Make-Up With Sunscreens are purchased primarily for their cosmetic effect - as make-up. Like Australia and Canada have done, FDA should recognize the dichotomy between the use of Final Make-Up With Sunscreens and the use of sunscreen products in which the sunscreen component is primary. As noted above, and in CTFA's Comments, sufficient flexibility should be provided to enable Facial Make-Up with Sunscreens to be

labeled in a common-sense way to recognize their primary use as make-up, while providing adequate information about the sunscreen component.

CONCLUSIONS

In conclusion, the Sunscreen Monograph should be revised to permit the labeling discussed above for Facial Make-Up With Sunscreens, including: (1) the modified labeling for Small Parts of the Face Products regardless of whether such products meet the requirements of 21 C.F.R. § 201.66(d)(10) (the 60% rule); (2) truthful and nonmisleading indications such as "protects against the harmful rays of the sun;" (3) appropriate directions and other useful information; and (4) the omission of the direction to consult a doctor for children under 6 months of age.

* * * * *

If you have any questions, please do not hesitate to contact the undersigned.

Respectfully submitted,

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Counsel to The Estēe Lauder Companies Inc.

Ivan J. Wasserman
Counsel to The Estēe Lauder Companies Inc.

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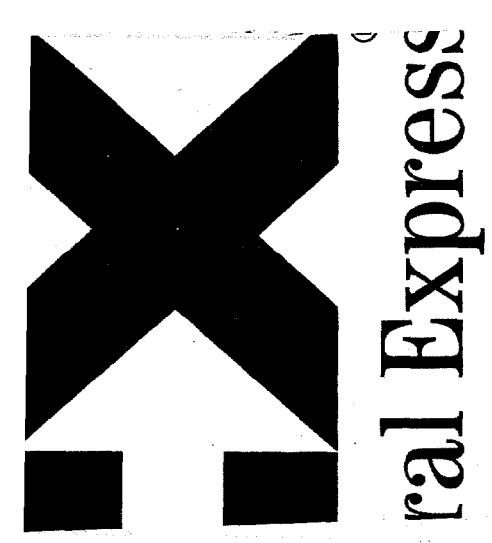

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